CHARGE: 402 (a) (3)—contained insect parts, rodent excreta, and rodent hairs; and, 402 (a) (4)—prepared under insanitary conditions.

DISPOSITION: 2–25–55. Default—destruction.

OLEOMARGARINE

22442. Oleomargarine. (F. D. C. No. 33816. S. No. 6–424–L.)

INFORMATION FILED: 11–7–52, Dist. Nebr., against Cudahy Packing Co., a corporation, Omaha, Nebr.

SHIPPED: 1–30–52, from Nebraska to Connecticut.

LABEL IN PART: (Carton) "Net Wt. 1 lb. Delrich E–Z Color Pak Vegetable Oleomargarine Prepared by The Cudahy Packing Co., General Offices, Omaha, Nebr."

CHARGE: 402 (b) (2)—a product containing less than 80 percent fat had been substituted for oleomargarine; and, 403 (g) (1)—the product contained less than 80 percent fat, the minimum permitted by the definition and standard of identity for oleomargarine.

PLEA: Not guilty.

DISPOSITION: The case was tried before the court without a jury on 2–26–54. On 3–31–55, after consideration of briefs and argument, the court handed down the following opinion, finding the defendant not guilty of the charge contained in count 1, guilty of the charge contained in count 2, and imposing a fine of $500, plus costs:

DELEHANT, *District Judge:* "After the filing of a stipulation waiving trial by jury, this case has been tried to the court. Typewritten briefs have been submitted and considered and the matter is ready for ruling and judgment.

"By an information in two counts the plaintiff charged the defendant, a Main corporation doing business in Nebraska, with the violation of the Federal Food Drug, and Cosmetic Act in the respects next disclosed.

"In Count I it was charged that on or about January 30, 1952, within this division of this district, the defendant caused to be introduced, and delivered for introduction, into interstate commerce at Omaha, Nebraska for delivery to Waterbury, Connecticut consigned to The Cudahy Packing Co., a number of cases, each of which contained a number of cartons of a food; that displayed upon the cartons was labeling which, among other things, consisted of the following printed and graphic matter:

Net Wt. 1 lb.
DELRICH
E–Z COLOR PAK
Vegetable
OLEOMARGARINE
Prepared by The Cudahy Packing Co.,
General Offices, Omaha, Nebr.;

that said food when caused to be introduced and delivered for introduction into interstate commerce 'was adulterated within the meaning of 21 U. S. C., 342 (b) (2) in that a product containing less than 80 percent by weight of fat had been substituted for oleomargarine, a product which must contain not less than 80 percent by weight of fat as prescribed by the definition and standard of identity for oleomargarine (21 C. F. R. 1949 Ed., 45.0 (a)).'

"Count II charged the defendant with exactly the same interstate shipment, concerning which it further charged that the food thus shipped 'was misbranded within the meaning of 21 U. S. C., 343 (g) (1) in that it purported to be and was represented as oleomargarine, a food for which a definition and standard of identity has been prescribed by regulations (21 C. F. R., 1949 Ed., 45.0 (a)) promulgated pursuant to 21 U. S. C. 341 and it failed to conform to said definition and standard in that Section 45.0 (a) of said definition

and standard provides that oleomargarine contains not less than 80 percent fat as determined by the method prescribed in said regulations, whereas said food contained less than 80 percent of fat as determined by such method.'

"Each of the counts further charged that on January 3, 1952 in Cr. 104–51 in this court the defendant was convicted of violation of the Federal Food, Drug, and Cosmetic Act which conviction had become final before January 30, 1952. Thereby, the application of the higher penalty provided in Title 21 U. S. C. A., Section 333 (a) was invoked.

"To each count the defendant pleaded not guilty.

"It may be observed, at the outset, and without needless discussion, that both parties correctly agree in their briefs that, even if the defendant be adjudged to be guilty under both counts, only one sentence may be imposed. Not only is the defendant charged with but a single act of transportation. If it violated the cited regulation the act or omission producing the violation occurred in a single respect and particular.

"The facts will first be found. In large part they are stipulated in writing. That stipulation is allowed by the court and the presently material facts agreed to in it are copied in detail in a footnote.[1] To a considerable extent, the

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[1] "1. That on or about January 30, 1952, the Cudahy Packing Company, a corporation, defendant herein, shipped from its plant at Omaha, Nebraska, by rail, in interstate commerce, to the Cudahy Packing Company, at Waterbury, Connecticut, 250 cardboard cases, each of which said cases contained 24 one-pound packages or cartons of a food, labeled in part as follows: '* * * DELRICH * * * OLEOMARGARINE * * *.'

"2. That the said 250 cardboard cases referred to in paragraph one hereof, each containing 24 one-pound packages or cartons of a food as described in paragraph one hereof, was delivered to and received by the Cudahy Packing Company, at Waterbury, Connecticut, on or about February 4, 1952.

"3. That at the time the said 250 cardboard cases, each containing cartons of a food as described in paragraphs one and two hereof were shipped from Omaha, Nebraska and delivered to and received by the Cudahy Packing Company at Waterbury, Connecticut, as set forth in paragraphs one and two hereof, some of the said cardboard cases were stamped with control number '0529,' others of said cardboard cases were stamped with control number '0530,' and some of the said cardboard cases were not stamped with any control number.

"4. That a number of the said cardboard cases containing cartons of a food as described and referred to in paragraphs one and two hereof, some of which bore stamp control number '0529,' some of which cases bore stamp control number '0530,' and some of which cases did not bear any stamp control number, were on hand and in the possession of the Cudahy Packing Company at Waterbury, Connecticut, on or about February 26, 1952, and also on or about May 9, 1952.

"5. That on or about February 26, 1952, Inspector William H. Phillips of the Food and Drug Administration, collected a sample consisting of ten one-pound packages or cartons of the said oleomargarine, each package or carton being taken from a different cardboard case which had been shipped from Omaha, Nebraska to Waterbury, Connecticut, as described in paragraphs one and two hereof, stamped with control number '0529' as described in paragraph three above, and after identifying each package or carton so taken with his initials, the date, and sample number '6–424 L,' and subdivision number (Said ten one-pound packages or cartons so taken were numbered 3, 5, 7, 9, 11, 14, 16, 19, 20, 21) and sealing the sample with an official seal used by the Food and Drug Administration, transmitted the said sample consisting of ten one-pound packages or cartons of said oleomargarine, to the Boston District Office of the Food and Drug Administration where the said sample was received by Analyst Gordon P. Trowbridge, Jr.

"6. That on or about March 11, 1952, Gordon P. Trowbridge, Jr., a graduate chemist, regularly employed in the Boston, Massachusetts office of the Food and Drug Administration, using the method of analysis recognized and approved by the Association of Official Agricultural Chemists, analyzed the ten one-pound packages or cartons, collected by Inspector William H. Phillips, as described in paragraph five hereof. In making this analysis, packages numbered 3 and 21 were each divided into two parts and numbered 3a and 3b, and 21a and 21b, and a separate analysis made of each of the parts. The results of the analyses thus made were as follows:

Sub. No.	*Fat*
3a	73.8
3b	73.9
5	80.7
7	80.7
9	81.1
11	80.3
14	81.3
16	80.9
19	81.1
20	80.0
21a	77.9
21b	----

The average per cent of fat for the ten subdivisions was 79.8.

"7. That on or about May 9, 1952, Inspector William H. Phillips, of the Food and Drug Administration, collected a sample consisting of 40 one-pound packages or cartons

of said oleomargarine, each package or carton being taken from a different cardboard case which had been shipped from Omaha, Nebraska, to Waterbury, Connecticut, as described in paragraphs one and two hereof, stamped with control number '0529,' as described in paragraph three above, and after identifying each carton with his initials, the date, the sample number 'Post Seizure 6–454 L' and the subdivision number, (1 to 40 inclusive), and sealing the sample with an official seal of the Food and Drug Administration, said Inspector William H. Phillips delivered the sample to the Boston District Office of the Food and Drug Administration where it was received by Analyst Gordon P. Trowbridge, Jr.

"8. That on or about May 9, 1952, and at the same time that Inspector William H. Phillips, of the Food and Drug Administration, collected the sample of oleomargarine consisting of 40 one-pound packages or cartons as described and referred to in paragraph seven hereof, William Gerard, an employee of the Cudahy Packing Company at Waterbury, Connecticut, also collected a sample of said oleomargarine consisting of forty one-pound packages or cartons, each of said forty one-pound packages or cartons so taken by Mr. Gerard were taken from the same forty cases stamped with control number '0529' from which Inspector William H. Phillips took the sample as described in paragraph seven hereof, and after Mr. Gerard had identified each of the forty one-pound packages or cartons with his initials, the date, a sample number, and like subdivision numbers as described in paragraph seven above, transmitted the same to the Food Research Laboratories, Inc., 48–14 Thirty-Third Street, Long Island City, New York.

"9. That on or about June 25, 1952, analyst Gordon P. Trowbridge, Jr., referred to in paragraph six above, using the method of analysis recognized and approved by the Association of Official Agricultural Chemists, analyzed subdivisions one through twenty, of the sample obtained by Inspector Phillips, as set forth in paragraph seven above.

"That on or about May 28, 1952, a chemist in the employ of Food Research Laboratories, Inc., 48–14 Thirty-Third Street, Long Island City, New York, using the method of analysis recognized and approved by the Association of Official Agricultural Chemists, analyzed the forty subdivisions, taken as a sample by William Gerard, as set forth and described in paragraph eight hereof.

"The results of the analysis of the contents of the packages or cartons of oleomargarine as to fat content thereof, by Analyst Gordon P. Trowbridge and by a chemist of the said Food Research Laboratories, Inc., are as follows:

Sub. No.	FAT CONTENT	
	Analyst Trowbridge	Food Research Laboratories, Inc.
1	81.1	81.49
2	81.0	80.91
3	81.1	81.53
4	81.4	81.29
5	80.8	81.16
6	81.2	81.58
7	81.1	81.02
8	81.2	81.21
9	80.7	80.83
10	76.2	76.62
11	77.9	78.62
12	74.8	78.62
13	81.0	81.45
14	80.0	80.36
15	80.9	81.45
16	76.7	77.07
17	74.0	74.11
18	80.7	80.50
19	80.9	80.91
20	80.5	80.76
21		79.99
22		81.01
23		80.95
24		81.27
25		81.16
26		81.07
27		81.16
28		80.06
29		81.13
30		80.98
31		80.84
32		81.44
33		80.53
34		80.86
35		79.96
36		81.35
37		81.49
38		80.79
39		79.17
40		80.82

defendant's manufacturing and shipping operations are conveniently reflected in a memorandum introduced and received as Exhibit 3 prepared from data provided by two of the defendant's principal witnesses. The facts—as distinguished from certain conclusions and argumentative material—set out in that memorandum are reflected in a footnote,[2] the contents of which may be considered as found by the court to be true.

"10. It is further stipulated and agreed that the scales which were installed in the Margarine Department of the Cudahy Packing Company, defendant herein, for the weighing of oil and other ingredients used in the manufacture of oleomargarine were the standard beam type scale which required the moving of weights on the beam to proper locations thereon for the determination of the weight of the oil and milk ingredients used, the scale operator would press slightly on the beam and as the scale beam rose to a nearly level position, the flow of oil and ingredient was cut down to a trickle by the manual operation or closing of a valve from the supply tank when the beam of the scale came into a level position, the flow of oil and other ingredients was completely cut off, by an employee manually closing the valve from the supply tank."

[2] "The oil used in the manufacture of the oleomargarine that was made on January 29, 1952, was refined hydrogenated deodorized cottonseed oil. The equipment and manufacturing methods and processes currently in use at that time and on that date were as set out below.

"This was oil that was commonly used all over the country in the manufacture of oleomargarine.

"Some producers of oleomargarine over the country use soybean or combination of cotton and soya.

"This oil was produced in Memphis.

"This oil is 100% fat. A small amount of soya lecithin, approximately 1/10th of 1%, is added as a preservative but this substance is also pure fat.

"The oil is received at the plant in tank cars and unloaded into storage tanks contained in the building. The oil as required is pumped from the storage tank into a scale tank, in the required amount for each batch. In this case 794 pounds of oil to each batch, after which the flow of oil in this scale tank discontinues. In other words, the man who is attending the weighing of the oil shuts off the supply of oil when the scale shows that there are 794 pounds of oil in the tank.

"This scale was a beam scale set for 794 pounds and when the beam came up showing that there were 794 pounds of oil in the tank the oil would be shut off. The scale would be set for 794 pounds of oil. As the amount of oil in the tank approximates that figure the man operating the scale would tap the beam with his finger to see whether or not it would come up easy and when it first began to show signs of being about to rise he would cut down the flow of oil so that as soon as the beam rose by itself he could shut off the oil and be sure that he had in the tank the required amount.

"This equipment consists of a stainless steel tank of approximately 1500 pounds capacity and is mounted directly upon the scale platform and is elevated above the floor in order that the contents could gravitate into the receiving tank after being weighed.

* * * * * * *

"The remainder of the ingredients in the margarine in this case consist of whole milk, salt emargol, sodium benzoate, diacetyl and Vitamin A. They are pre-mixed in separate tanks provided for that purpose. After these ingredients have been thoroughly mixed and are incorporated 206 pounds of this mixture is pumped into the tank already holding 794 pounds of oil. The scale tank is equipped with a mechanical mixer where pre-mixing is accomplished before transferring the batch to the receiving tank. Here the pre-mixing of the oil and other ingredients is obtained before transferring to the receiving tank. At this time the scale beam is set at 1000 pounds and the mixture of the ingredients mentioned above is pumped into the tank until the 1000 pound total weight is reached.

"The following is the procedure in which the ingredients, other than oil, are proportioned in the proper amounts for margarine. The following quantities are used to make one batch of mixture of these ingredients—

Whole milk	880 pounds.
Salt	160 pounds.
Emargol	26½ pounds.
Sodium Benzoate	5¼ pounds.
Diluted Diacetyl	192 cc.
Vitamin A	236.5 grams.

The weight of the above ingredients is arrived at as follows:

Milk: This item is received from the creameries in cans containing 80 pounds each; 11 cans making a total of 880 pounds.

Salt, emargol and sodium Benzoate obtained by actual weighing of each ingredient at time of adding to the mixing tank.

Diluted Diacetyl, being a liquid, quantity was arrived at by measurement on a chemist's graduated tube.

Vitamin A is purchased from the manufacturer in containers, each one holding the required amount for each batch, namely, 236.5 grams. The entire contents of each of these containers is added to each batch.

"After the above ingredients are added to the mixing tank a mechanical electrically operated mix device is used to obtain complete mixture. This mixer is operated continuously for a minimum time of thirty minutes.

"After weighing the batch of oil and milk mixture into the scale or weighing tank a valve in the bottom of the tank is opened and the contents permitted to drain by gravity

"The method, outlined in footnote 2, of weighing ingredients for the manufacturer's mixture is a regularly employed and efficient technique. It is true that some manufacturers employ an electrically operated type of scale, which is superior in sharpness and accuracy; but the manually operated scale is quite adequate.

"During the defendant's manufacture of oleomargarine at its Omaha plant, the product was made in batches of one thousand pounds each. From twenty to twenty-five batches were customarily made each day. And two mixing tanks were maintained for the preparation of white oleomargarine. The product of an individual batch could be identified while it remained in the Omaha warehouse, although no exact marking was made of the product of each batch. The numbers O529 and O530 are control numbers in code used by the defendant to identify the day the marked product was made. 'O' signifies Omaha as the plant; '5' signifies January; and '29' signifies the day of the month. Therefore, 'O529' shows that the product in the package thus stamped was made at Omaha on January 29. Comparable analysis might be made of 'O530.' However, it is obvious that in view of the number of batches processed each day, a common control number on two packages would not necessarily

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into the stainless steel receiving tank, circular in form and with a sloping bottom. After the entire batch of 1000 pounds has been dropped into the receiving tank mechanical mixing is begun by means of a lightening mixer. This mixer consists of a shaft with a propeller at the end which revolves at a high rate of speed causing a complete turmoil and rotation of the tank contents. Mixing ordinarily takes twenty minutes.

"After the mixture of oil, milk and other ingredients had been mixed as described in the paragraph above the mixture was pumped into a machine known as a votator. The purpose of the votator is to refrigerate, solidify and homogenize the material. This is accomplished by means of direct expansion ammoniated refrigeration system. The temperature of the mixture going into the votator was 105–110 degrees Fahrenheit and a temperature of 58 degrees Fahrenheit leaving the votator. At a temperature of 58 degrees the mixture is in a semi-liquid form and in this condition transferred by means of a pumping and measuring device through filling pipes that delivered 16 ounce (one pound) of mixture into plastic bags. The plastic bags then pass by means of a conveyor through a sealing device where the open end was closed by passing the bag through two belts, one hot, the other cold; the pressure causing the bag to seal. From this point the bags were placed in cartons and the cartons packed in shipping containers.

"This piece of equipment consisted of two parts, namely, the A Unit in which the mixture is chilled and solidified. The mixture then passes to the second step or B Unit where it is homogenized to the point where it is extruded as a smooth semi-liquid substance.

"Samples were obtained by the chemist as the oleomargarine was extruded from the filling pipes to the plastic bags.

"As of January 1952 the equipment used by Cudahy was standard equipment over the country and the methods of mixing and weighing were standard methods in general used over the country in well regulated and well operated oleomargarine plants.

"Inasmuch as, next to oil, moisture is the principal substance in margarine, it is a known fact that where moisture content is within the proper range then the margarine will show the proper fat content to meet Government requirements. Experience has shown that where the moisture content does not exceed 15.25% of the total the fat content will be in excess of 80%. In order to assure ourselves that the proper fat content was present it is our custom to obtain moisture percentages on a number of batches of each day's manufacture. As a control analysis to substantiate the results of the moisture analysis an analysis to arrive at the percentage of each ingredient present in the oleomargarine was conducted on several samples each day.

"The moisture test was conducted as follows: The chemist would weigh 10 grams of the oleomargarine with a regulation chemist balance for this purpose. The margarine weighed for test purposes was placed in a thin aluminum cuplike device and placed on top of an electric hot plate and subjected to heat until all of the moisture in the margarine leaves the margarine in the form of steam. The remaining substance in the cup is then weighed on the scale balance and the percentage of moisture drawn off in the form of steam is then calculated.

"The tests for fat content were made by the chemist. The chemist used the standard test that was in use all over the country.

"At one time Delrich Margarine in the E–Z Pak bag was manufactured with non-fat dried milk solids to which water was added to obtain reconstituted dried skim milk. Inasmuch as this reconstituted milk did not contain any fat whatever the oil ingredient in the margarine was held at 80% of the total, or 800 pounds of oil to each 1000 pound batch. Sometime during 1951 in order to improve the quantity of Delrich margarine we established the practice of using whole sweet milk instead of reconstituted dried skim milk solids. Whole sweet milk contains a minimum of 3.5% butterfat and the fat content in the milk was added to the 794 pounds of oil to arrive at a total of 80% plus fat in the margarine. The ingredient known as emargol is also a fat substance and its presence would also contribute to adding to the total percentage of fat to the margarine.

"Ever since October of 1951 we have been using 794 pounds of oil and 206 pounds of milk mixture to each batch, and experience based on daily tests had demonstrated that that mixture would produce oleomargarine containing more than 80% fat."

or even with reasonable probability signify that the contents of the two packages were made in a single batch.

"It is reasonably found from the oral testimony that the considerable intervals between the shipment on January 29, 1952 and the making of the several analyses reflected in footnote 1, e. g. March 11, 1952, May 9, 1952, and May 28, 1952, did not result in substantial change in the fat content of the product. Some factors inhering in that delay would tend to cause a higher fat content, others a lower one. But it fairly appears that the overall change and difference would be slight, if any. The court, therefore, considers, and counsel seem also to consider, the stipulated tests to be fairly reflective of the fat content of the several tested samples as of the critical time of shipment. Thus, of the thirty samples or packages tested in behalf of the plaintiff seven contained less than eighty percent by weight of fat. And of the forty packages or samples tested in behalf of the defendant eight disclosed less than eighty percent by weight of fat. Of the ten samples first taken and tested in behalf of the plaintiff, the average percentage of fat was 79.8. Of the twenty samples later taken and tested in behalf of the plaintiff the average percentage of fat was 79.66 and of the forty samples taken and tested in behalf of the defendant the average percentage of fat was 80.43.

"The defendant, on November 23, 1949, in No. Cr. 101–49 in this court was, upon its plea of nolo contendere, convicted of the violation of the Federal Food, Drug, and Cosmetic Act upon each of eight counts of an information, of which four counts charged it with the introductions into interstate commerce of oleomargarine that was adulterated in that it contained less than eighty percent by weight of fat and four counts charged it with the introduction of such oleomargarine as being misbranded, and was adjudged and sentenced to pay a fine upon each such count and to pay the costs of prosecution. That conviction had become final before January 29, 1952. While this conviction was stipulated and was testified to upon the trial, it was not charged in the information. Therefore, the court, beyond finding that it occurred, attributes no present significance to it.

"Thereafter, on January 3, 1952, the defendant in No. Cr. 104–51 in this court was, upon its plea of nolo contendere convicted of the violation of the Federal Food, Drug and Cosmetic Act upon each of four counts of an information, of which two counts charged it with the introduction into interstate commerce of a number of cases of food which were adulterated within the meaning of 21 U. S. C. 342 (b) (2) and two counts charged it with the introduction into interstate commerce of a number of cases of food which were misbranded within the meaning of 21 U. S. C., 343 (g) (1), and was adjudged and sentenced to pay a fine upon each of such counts and to pay the costs of prosecution. That conviction had become final before January 29, 1952. It is the conviction pleaded in the several counts of the present information.

"As of the time of the present trial the defendant was not engaged in the manufacture of oleomargarine at its Omaha plant, but was utilizing a Chicago plant for that purpose. Prior to the prosecution in No. Cr. 101–49, the defendant had for some time made oleomargarine at its Omaha plant. But at about that time, though not in consequence of the prosecution, it discontinued that practice. The reason for the discontinuance was the comparative smallness of the Omaha plant and the greater size of its Chicago facilities. Some time later manufacturing was resumed at Omaha. The prosecution in No. Cr. 104–51 followed. Then, the defendant made material change in its measuring and weighing and mixing methods, and with those changes continued to make the product at Omaha until early in February, 1952, when the use of the Omaha plant for the making of oleomargarine was again abandoned. A witness for the defendant attributed the reason for that change to the large equipment at Chicago. The motive, however, is quite immaterial to the court's present inquiry. So, too, for that matter is the change itself, at least on the issue of guilt or innocence.

"The sections of the statutes and the regulation brought into the controversy may appropriately be recalled at this point.

"Title 21 U. S. C. A., Section 331 (a) is first quoted:

> The following acts and the causing thereof are hereby prohibited:
>
> (a) The introduction or delivery for introduction into interstate commerce of any food . . . that is adulterated or misbranded.

"The penalty for such violation is defined in Title 21 U. S. C. A., Section 333 (a):

> Any person who violates any of the provisions of section 331 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

"The only charge of adulteration made in the information is laid under Title 21 U. S. C. A., Section 342 (b) (2) which is in these words:

> A food shall be deemed to be adulterated—(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor.

"Not because violation of them is charged, but for their conceivable significance upon the meaning of section 342 (b) (2), other subsections of section 342 are now quoted. Subsections (b) (3) and (4) follow:

> (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

And subsection (e) having explicit reference to oleomargarine is in this language:

> (e) If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

"For present purposes, misbranding is thus defined by Title 21 U. S. C. A., Section 343 (g) (1):

> A food shall be deemed to be misbranded . . . (g) if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 341, unless (1) it conforms to such definition and standard.

"The foregoing reference to Title 21 U. S. C. A., Section 341 prompts the following quotation from subsection (a) of that section:

> (a) Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: . . .

"Within that grant of authority the Secretary through proper delegation prior to January 29, 1952 had defined, and prescribed standards of identity for oleomargarine which were effective on that date. See 21 C. F. R. Section 45.0, 1949 Ed.[3] Generally, the regulation declares (subsection (a)), that

> Oleomargarine is the plastic food prepared with one or more of the optional fat ingredients named in subparagraph (1), (2), (3), or (4) of this paragraph.

That language is followed by the designation of fat ingredients that admittedly include cottonseed oil which was the one employed by the defendant in the making of the challenged oleomargarine. Then, touching the prescribed quantity of a designated ingredient it is declared that:

> The finished oleomargarine contains not less than 80 percent fat, as determined by the method prescribed in "Official and Tentative Methods of

[3] For the regulation in current form, see 21 C. F. R. 45.1 Cumulative Pocket Parts to 1949 Edition.

Analysis of the Association of Official Agricultural Chemists," 4th Edition 1935 page 289, or 5th Edition 1940 page 298.

In this trial no issue was made upon the adequacy under the last quoted language of the methods of testing pursued by both the plaintiff and the defendant. The stipulation, see footnote 1, appears to foreclose any such question.

"Beyond the facts as found, the questions before the court are few and, as it would seem, fairly simple. The first and most vital one is whether the product contained in defendant's shipment of January 29, 1952 [4] was violative of the definition and standard made and erected by 21 C. F. R., Section 45.0 (a). For unless it was, both counts of the information must necessarily fall. Whether validly or not, both of them are poised upon it. The product is thus violative if the failure of the contents of fifteen of the tested one-pound packages to contain as much as eighty percent by weight of butterfat constitutes a violation. This court considers that it does.

"Counsel for the defendant argues vigorously that there were altogether several hundred packages in the shipment stamped with control number 0529 of which the contents of only seventy were tested at all; and that of the seventy only fifteen failed to meet the eighty percent test. The others tested either met or surpassed it. And the proofs show nothing of the ingredients of the much larger number of untested packages. The argument proceeds to assert first, that the over all average fat content by weight of the tested product under control number 0529 somewhat exceeded eighty percent, and, secondly, that it may fairly be assumed that the entire product bearing that control number also exceeded the eighty percent requirement. Upon the latter phase it is recognized that no deficiency in the untested portion of the shipment is affirmatively established by the proof.

"But the argument in its entirety is unsound. The cited regulation applies to any oleomargarine irrespective of the size of its mass, or the manner of its packaging, or whether it constituted all or only a part or parts of a shipment. The contents of each of the fifteen packages included less than eighty percent of fat by weight. With some the deficiency was very slight, less than one percent. With others it was greater, extending to slightly more than six percent. As to the contents of those packages the deficiency manifestly exists.

"That deficiency is not to be put aside upon the assumption that the entire batch out of which the samples were taken contained not less than eighty percent of fat. To begin with the assumption is just that. It is unproved and unsupported by proof except that dealing with the technique of weighing and mixing. And that is far from conclusive. It seems to be true that all oleomargarine bearing control number 0529 was made at Omaha on January 29, 1952. But from twenty to twenty-five batches of the product were made there daily. Therefore, no assurance exists that all of the shipped product bearing the control number 0529 was made in the same batch. The probabilities are all to the contrary. One may not say, from any data before the court, what the average fat content was of the batch out of which the contents of any sampled package were taken. More to the point, the cited statutes, considered together, deal with the shipment of offending products in any quantity, not with a general average of fidelity to standard or definition of the manufactured mass out of which the deficient product emerged.

"Nor may the adequacy of the larger portion of the product actually shipped immunize the shipper from liability on account of the deficiency of some, though few, separately packaged and distinct units of the shipment. The statute is aimed at any such shipment of a deficient product. And it is not satisfied by the circumstance that much, even most, of the product contemporaneously shipped is equal to, or above, the standard. The reason is clear. Oleomargarine is shipped for ultimate resale as human food in the individual one pound packages to ultimate consumers. Each purchaser is concerned only with the excellence of the one pound he buys. If it is deficient his plight is not improved because nearly every other package in the

[4] The disparity between that date and January 30, 1952, designated in the indictment is noted, but is regarded as wholly immaterial.

shipment contained material that was fully equal to the prescribed standard.

"The argument involves the different, but somewhat related, thoughts that (a) the de minimis rule should be applied here,[5] and (b) the court should allow a measure of tolerance in meeting the stern eighty percent test. Both of those thoughts neglect the effect and language of Title 21 U. S. C. A., Section 341 (a), supra, and of 21 C. F. R. 45.0 (a), supra. The cited section gave to the Secretary sweeping power 'to fix and establish a reasonable definition and standard of identity' for such products. And the Secretary, in the exercise of that authority, defined the product as containing 'not less than 80 percent fat.' [Emphasis added.] The underscored words appear conclusively to repel the contention that courts should allow a small indulgence in administering the regulation and also the argument for the application of the de minimis rule, by which a 'little violation' would be judicially forgiven. If the promulgator of the regulation considered that a degree of tolerance should be allowed in its administration he might have made provision accordingly. He did not. 'Not less than eighty percent' means exactly that. The courts are required to follow, and are not allowed either to amend or to nullify such regulations. Instructive in this connection is *Land O'Lakes Creameries* v. *McNutt* (8 cir) 132 F. (2) 653 in which the statute in question and the basic regulation defining and fixing standards for oleomargarine were examined and approved.

"Considerations rooted in its purpose and objective have prompted the federal courts to a generally rigid enforcement of the Food, Drug and Cosmetic Act and to a reasonably strict interpretation of its meaning. *United States* v. *Dotterweich* 320 U. S. 277; *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U. S. 218; *United States* v. *716 Cases . . . . . of Tomatoes* (10 cir.) 179 F (2) 174; *Bruces Juices* v. *United States* (5 cir.) 194 F (2) 935; *United States* v. *36 Drums of Pop'n Oil* (5 cir.) 164 F (2) 250; *United States* v. *1851 Cartons . . . . . Whiting Frosted Fish* (10 cir.) 146 F (2) 760, 144 F (2) 356, 146 F (2) 760 (reversing 55 F. Supp. 343); *338 Cartons . . . . . of Butter* v. *United States* (4 cir.) 165 F (2) 728; *A. O. Andersen & Co.* v. *United States* (9 cir.) 284 F. 542; *United States* v. *133 cases of Tomato Paste* (D. C. Pa.) 22 F. Supp. 515; *Libby McNeill & Libby* v. *United States* (2 cir.) 148 F (2) 71; *Byrd* v. *United States* (5 cir.) 154 F (2) 62.

"Counsel have helpfully made the court aware of some opinions in which, if not expressly, at least in substance, the de minimis rule has been followed in actions dealing with foods. But they seem not to be presently instructive. Some of them deals with the allowance of minor tolerances in the matter of adulteration where no administrative definition or prescription of standard was involved. In them there was no question of the judicial alteration or disregard of legislative determination. Others had to do with the government's attempts to condemn altogether large shipments of a product in which only a minor and easily identifiable portion was odious to the law. In them the major demand of the United States was rejected but generally the offending units of the shipments were forfeited. Finally, in at least one, as counsel for the defendant with laudable professional candor acknowledges, the indulgent judgment of the district court was reversed on appeal. See *United States* v. *1851 Cartons . . . . . Whiting Frosted Fish* (10 cir.) 144 F (2) 356, 146 F (2) 760 (reversing 55 F. Supp. 343).

"Notwithstanding its conclusion that the product shipped did not conform to the definition and standard promulgated for it, the court is compelled to conclude that the government has failed to prove adulteration, which is the only violation of the Act charged in Count I.

"It may be repeated that adulteration is charged only under Title 21 U. S. C. A., Section 342 (b) (2). No violation of subsections (b) (3) and (4), or either of them, is asserted. Similarly, it is not charged that Title 21 U. S. C. A., Section 342 (e) dealing specifically with oleomargarine was violated.

"Now, Title 21 U. S. C. A., Section 342 (b) (2) has to be read in association with its related subsection (b) (1). It makes incorporating reference to subsection (b) (1), as a rereading of the two subsections, supra, will readily demonstrate. The act of violation thus envisaged manifestly contemplates the *withdrawal* from a product of a 'valuable *constituent*' of it, and the *substitution*

[5] Which the defendant explicitly argues.

of another substance for the withdrawn constituent. The government's specification of the violative act, however, is something quite different. It asserts that 'a product containing less than 80 percent by weight of fat had been substituted for oleomargarine,' which by definition must contain not less than 80 percent by weight of fat. What is really charged is not the adulteration of the product by the withdrawal and substitution of ingredients, but the substitution of an altogether different final product. The charge has nothing to do with the removal or substitution of ingredients.

"Nor do the proofs. The ingredients required were all present, but one of them was present in slightly reduced quantity and others presumably in larger quantities. The government argues that this variation in quantities constitutes 'economic adulteration.' That term has crept into some of the decisions to characterize the skimping in manufacture upon expensive ingredients and the corresponding enlargement of cheaper substances. *United States v. 36 drums of Pop'n Oil* (5 cir) 164 F. (2) 250; *United States v. 716 Cases . . . . . Tomatoes* (10 cir) 179 F. (2) 174. In the thinking of those cases, and the argument of the government here, some emphasis is placed on the higher cost of the ingredient whose quantity is diminished in comparison with the substituted material. Therein lies the motive and the malice of the alteration. But in the present record the evidence draws no contrast between the cost of cottonseed oil and that of whole milk, evidently the two ingredients principally involved. And the court can not take judicial notice of such difference as may exist or of its direction, as was apparently done without difficulty in *United States v. 716 Cases*, supra, where the liberally supplied ingredient was water, and in *United States v. 36 Drums*, supra, where the choice lay between mineral oil and melted butter. So, the court considers the argument of 'economic adulteration' to be fatally defective in its supporting proof of economic impact.

"Another obstacle to conviction under Count I arises because it assumes that resort may be had in support of a charge under Title 21 U. S. C. A., Section 342 (b) (2) to 21 C. F. R. Section 45.0 (a) promulgated under authority of Title 21 U. S. C. A., Section 341 (a). Unlike the section of the statute defining misbranding, (Title 21 U. S. C. A., Section 343(g)) the section within which Count I was framed does not refer to such regulatory definition or standard as a canon or test of adulteration. This thought is not novel. In *Bruce's Juices v. United States* (5 cir) 194 F. (2) 935, the learned Chief Judge of the Fifth Circuit asserts:

> . . . . . as clearly appears on its face, Sec. 341 invoked by appellant has no relation to, no connection with, the adulteration provisions of the Act. *United States v. 36 Drums of Pop'n Oil* (5 cir) 164 F. (2) 250. It relates to, its office is in connection with the misbranding provision, Section 343 (h).

"In reaching its conclusion upon Count I adverse to the plaintiff, the court has not approved an argument of the defendant that Title 21 U. S. C. A., Section 342 (e) directly relating to oleomargarine, exclusively governs the adulteration of that product. That subsection was brought into the Food, Drug and Cosmetic Act by the Act of March 16, 1950, legislation dealing especially with the taxation of oleomargarine and inspired by its position competitive with butter. Its legislative history is assembled in *2 U. S. Code Congressional Service, pages 1968 to 1982*, both inclusive. From page 1980, the following excerpt is taken from the conference report:

> Section 3 (d) of the bill (Senate amendment No. 11).
>
> Senate amendment No. 11, as amended and agreed to by the committee of conference, adds a new provision to the bill the effect of which is to amend section 402 of the Federal Food, Drug and Cosmetic Act by adding thereto a new subsection (e). The provision is as follows:
>
> "(e) If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine, or margarine, or butter is otherwise unfit for food."
>
> This section, as agreed to by the conferees, adds nothing to section 402 (a) (3) of the Federal Food, Drug, and Cosmetic Act as it has been consistently interpreted and construed by the administrative officials charged

with its enforcement and by the Federal courts. It was adopted by the conferees, however, so as to make abundantly clear the intent of Congress that butter, oleomargarine, and margarine and all of their raw materials used in the manufacture of such butter, oleomargarine, and margarine should be subject to precisely the same standard of purity and to the same type of inspection.

It was not the intent of the conferees by adopting this new provision to weaken in any way the provisions of existing law as they have been interpreted and construed which provide that any food shall be deemed to be adulterated food (including all components thereof) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.

The amendment merely added a clarifying subsection dealing specifically with 'oleomargarine or margarine or butter.' It did not withdraw them from the general provisions against adulteration theretofore and still in effect in respect of all food.

"Accordingly, a judgment of acquittal upon Count I is being made and given.

"But by Title 21 U. S. C. A., Section 343 (g), supra, it is positively declared that a food is misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations under Section 341, unless it conforms to such definition and standard. The contents of the tested packages found short of the eighty percent requirement in respect of fat (a) purported to be and were represented to be oleomargarine, for which a definition and standard of identity had been so prescribed, and (b) did not conform to such definition and standard. Therefore, by the plain terms of Section 343 it was misbranded. And its shipment, thus misbranded, unquestionably violated section 331.

"A judgment of guilty must therefore be made and given upon Count II.

"The matter of sentence remains. The defendant being a corporation, only a fine is appropriate. By Title 21 U. S. C. A., Section 333, the maximum allowable fine is $1,000.00 with the proviso that, for a violation committed after the defendant's conviction under the section and the finality of such conviction, the fine may be as high as $10,000.00.

"Despite the court's findings, supra, concerning No. Cr. 104-51 in this court, it is not considered that the fine should be made notably heavy. The violation now before the court was not attributable to hostility or indifference to the applicable statutes or regulation or to contempt of the rights of the public. It occurred despite a bona fide effort to comply with both the statutes and the regulation, though probably with the allowance of a margin of safety that was practicably too small or nonexistent.

"In the circumstances the sentence is that the defendant pay a fine of five hundred dollars and the costs of this case."

POULTRY

22443. Dressed poultry. (F. D. C. No. 37374. S. No. 11-861 M.)

QUANTITY: 1,600 lbs. in 21 crates at Newark, N. J.

SHIPPED: 11-9-54, from Frankford, Del., by Allied Poultry Processors Co.

LABEL IN PART: (Crate) "Acme Brand Fresh Killed Ice Packed Poultry Fresh Dressed Extra Fancy New York Dressed Maryland Poultry Acme Poultry Corp., Berlin, Maryland."

LIBELED: On or about 12-1-54, Dist. N. J.

CHARGE: 402 (a) (3)—consisted of birds contaminated with fecal matter, extensively bruised birds, and green struck birds when shipped.

DISPOSITION: 3-29-55. Default—destruction.

22444. Dressed poultry. (F. D. C. No. 37657. S. No. 2-793 M.)

QUANTITY: 1,007 lbs. in 16 crates at Boston, Mass.

SHIPPED: 2-1-55 from Goffstown, N. H., by Karanikas & Sons.